

AMENDED CLAIMS

[received by the International Bureau on 8 February 1999 (08.02.99);
original claims 17-21 replaced by amended claims 18-22;
remaining claims unchanged (4 pages)]

- 5
10
15
20
25
30
1. An immune globulin preparation comprising an immune globulin and at least one non-ionic surface active agent, said one or more non-ionic surface active agent(s) in a concentration sufficient to increase the serum half-life of the immune globulin.
2. The preparation according to claim 1 wherein the immune globulin is anti-Rh₀D immune globulin.
3. The preparation according to claim 2 wherein the anti-Rh₀D immune globulin has an IgG purity of greater than about 95% and a monomeric protein content of greater than about 94%.
4. The preparation according to claim 3 which is aqueous.
5. The preparation according to claim 1 wherein the immune globulin is anti-c immune globulin.
6. The preparation according to claim 5 wherein the anti-c immune globulin has an IgG purity of greater than about 95% and a monomeric protein content of greater than about 94%.
7. The preparation according to claim 6 which is aqueous.
8. The preparation according to claim 1 wherein the concentration of the immune globulin is about 2 weight percent to about 10 weight percent.
9. The preparation according to claim 1 wherein the one or more non-ionic surface active agent(s) is(are) a sorbitan ester of a fatty acid.

10. The preparation according to claim 9 wherein the non-ionic surface active agent(s) is(are) selected from the group consisting of sorbitan monolaurate, sorbitan monopalmitate, sorbitan monostearate, sorbitan tristearate, sorbitan monooleate, and sorbitan trioleate.

11. The preparation according to claim 1 wherein the one or more non-ionic surface active agent(s) is(are) a polyoxyethylene sorbitan ester of a fatty acid.

12. The preparation according to claim 11 wherein the non-ionic surface active agent(s) is(are) selected from the group consisting of polyoxyethylene (20) sorbitan monolaurate, polyoxyethylene (4) sorbitan monolaurate, polyoxyethylene (20) sorbitan monopalmitate, polyoxyethylene (20) sorbitan monostearate, polyoxyethylene (4) sorbitan monostearate, polyoxyethylene (20) sorbitan tristearate, polyoxyethylene (20) sorbitan monooleate, polyoxyethylene (5) sorbitan monooleate, and polyoxyethylene (20) sorbitan trioleate.

13. The preparation according to claim 1 wherein two or more non-ionic surface active agents are selected from the group consisting of polyoxyethylene (20) sorbitan monolaurate, polyoxyethylene (4) sorbitan monolaurate, polyoxyethylene (20) sorbitan monopalmitate; polyoxyethylene (20) sorbitan monostearate, polyoxyethylene (4) sorbitan monostearate, polyoxyethylene (20) sorbitan tristearate, polyoxyethylene (20) sorbitan monooleate, polyoxyethylene (5) sorbitan monooleate, and polyoxyethylene (20) sorbitan trioleate, sorbitan monolaurate, sorbitan monopalmitate, sorbitan monostearate, sorbitan tristearate, sorbitan monooleate, and sorbitan trioleate.

14. The preparation according to claim 1 wherein the concentration of the one or more non-ionic surface active agent(s) is(are) about 0.01 weight percent to about 0.5 weight percent.

15. The preparation according to claim 1 wherein the aqueous immune globulin preparation is lyophilized to form a dry powder preparation.

5 16. An aqueous immune globulin preparation wherein the immune globulin has an increased serum half-life comprising:
about 3-8% human anti-Rh₀D immune globulin with an IgG purity of greater than 95% and a monomeric protein content of greater than 94%;

10 sodium chloride at about 0.25% (w/v);
very low level buffer with essentially no ionic strength;
Polysorbate 80 at about 0.01% to about 0.5% (w/v); and
L-glycine at about 0.1M.

15 17. The preparation according to claim 1 wherein the one or more non-ionic surface agents are selected from the group consisting of glyceryl monooleate; and a polyvinyl alcohol.

20 18. A use of an immune globulin preparation according to any one of claims 1 to 17 to increase the serum half-life of an immune globulin.

25 19. A use of an immune globulin preparation according to any one of claims 1 to 17 to reduce the elevation of neutrophil counts.

20. A method of increasing the serum half-life of an immune globulin comprising administering an immune globulin preparation according to claims 1 to 17 to an animal in need thereof.

30 21. A method of reducing the elevation of neutrophil counts in a recipient of immune globulin comprising administering an immune globulin preparation according to claims 1 to 17 to an animal in need thereof.

22. A method according to claim 20 or 21 wherein said immune globulin preparation is administered intravenously.

add C'